



10/536992
PCT/GB2003/005424



INVESTOR IN PEOPLE

PRIORITY DOCUMENT

SUBMITTED OR TRANSMITTED IN
COMPLIANCE WITH RULE 17.1(a) OR (b)

The Patent Office
Concept House
Cardiff Road
Newport
South Wales
NP10 8QQ

RECEIVED

22 JAN 2004

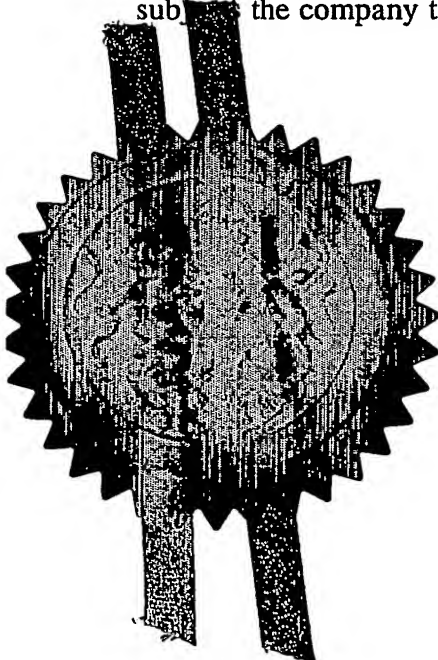
WIPO PCT

I, the undersigned, being an officer duly authorised in accordance with Section 74(1) and (4) of the Deregulation & Contracting Out Act 1994, to sign and issue certificates on behalf of the Comptroller-General, hereby certify that annexed hereto is a true copy of the documents as originally filed in connection with the patent application identified therein.

In accordance with the Patents (Companies Re-registration) Rules 1982, if a company named in this certificate and any accompanying documents has re-registered under the Companies Act 1980 with the same name as that with which it was registered immediately before re-registration save for the substitution as, or inclusion as, the last part of the name of the words "public limited company" or their equivalents in Welsh, references to the name of the company in this certificate and any accompanying documents shall be treated as references to the name with which it is so re-registered.

In accordance with the rules, the words "public limited company" may be replaced by p.l.c., plc, P.L.C. or PLC.

Re-registration under the Companies Act does not constitute a new legal entity but merely subjects the company to certain additional company law rules.



Signed

W. E. Jones

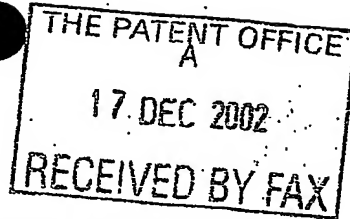
Dated 8 January 2004

BEST AVAILABLE COPY

An Executive Agency of the Department of Trade and Industry

Patents Form 1/77

Patents Act 1977
(Rule 90)



The
Patent
Office

1/77

Request for grant of a patent

(See the notes on the back of this form)

The Patent Office

Cardiff Road
Newport
Gwent NP10 8QQ

1. Your reference ST/X

2. Patent application number
(The Patent Office will fill in this part)

0229345.4

17 DEC 2002

3. Full name, address and postcode of the or of
each applicant (underline all surnames)

SAFE-T-LIMITED
LAUREL HOUSE
CROIT-Y-QUILL
LONAN
ISLE OF MAN IM4 7JD

Patents ADP number (*if you know it*)

If the applicant is a corporate body, give the
country/state of its incorporation

ISLE OF MAN

6101422001

4. Title of the invention

HOLLOW NEEDLE APPLICATORS

5. Name of your agent (*if you have one*)

David Dodd

"Address for service" in the United Kingdom
to which all correspondence should be sent
(including the postcode)

T N P Services
P O Box 13
Manchester
M30 9FZ

Patents ADP number (*if you know it*)

7418650003

6. If you are declaring priority from one or more
earlier patent applications, give the country
and the date of filing of the or each of these
earlier applications and (*if you know it*) the or
each application number

Country	Priority application number (<i>if you know it</i>)	Date of filing (<i>day/month/year</i>)
---------	--	---

7. If this application is divided or otherwise
derived from an earlier UK application,
give the number and the filing date of
the earlier application

Number of earlier application	Date of filing (<i>day/month/year</i>)
-------------------------------	---

8. Is a statement of inventorship and of right
to grant of a patent required in support of
this request? (*Answer 'Yes' if:*

YES

- a) any applicant named in part 3 is not an inventor, or
 - b) there is an inventor who is not named as an applicant, or
 - c) any named applicant is a corporate body
- See note (d)

Patents Form 1/77

Patents Form 1/77

9. Enter the number of sheets for any of the following items you are filing with this form. Do not count copies of the same document

Continuation sheets of this form	--
Description	15
Claim(s)	-
Abstract	-
Drawing(s)	7 only

10. If you are also filing any of the following, state how many against each item,

Priority documents	-
Translations of priority documents	-
Statement of inventorship and right to grant of a patent (Patents Form 7/77)	-
Request for preliminary examination and search (Patents Form 9/77)	-
Request for substantive examination (Patents Form 10/77)	-
Any other documents (please specify)	-

11.

I/We request the grant of a patent on the basis of this application

Signature

Date

17 December 2002

12. Name and daytime telephone number of person to contact in the United Kingdom

David Dodd

0161 736 7719 (tel/message)

0161 736 3331 (fax/message)

Warning

After an application for a patent has been filed, the Comptroller of the Patent Office will consider whether publication or communication of the invention should be prohibited or restricted under Section 22 of the Patents Act 1977. You will be informed if it is necessary to prohibit or restrict your invention in this way. Furthermore, if you live in the United Kingdom, Section 23 of the Patents Act 1977 stops you from applying for a patent abroad without first getting written permission from the Patent Office unless an application has been filed at least 6 weeks beforehand in the United Kingdom for a patent for the same invention and either no direction prohibiting publication or communication has been given, or any such direction has been revoked.

Notes

- If you need help to fill in this form or you have any questions, please contact the Patent Office on 0645 500505.
- Write your answers in capital letters using black ink or you may type them.
- If there is not enough space for all of the relevant details on any part of this form, please continue on a separate sheet of paper and write "see continuation sheet" in the relevant part(s). Any continuation sheet should be attached to this form.
- If you have answered "Yes" Patents Form 7/77 will need to be filed.
- Once you have filled in the form you must remember to sign and date it.
- For details of the fee and ways to pay please contact the Patent Office.

Patents Form 1/77

TITLE: HOLLOW NEEDLE APPLICATORS

FIELD OF INVENTION

This invention relates to hollow needle applicators suitable for administering cartridged drugs etc in a manner assuring retraction of the needle after use.

In using the term "drugs etc" herein, there is no intention to limit application of this invention to drugs or medicaments as such. This invention is seen as generally applicable to any usefully injectable substance; and to injecting into any appropriate receiver, i.e. whether or not that is tissue of a human or even animal subject.

Suitability for use in administering drugs does, however, bring in certain constraining desiderata. One is for exceptional reliability including as to accuracy of the administered quantity of drug precisely as and where intended. Another is for minimising costs of applicators as essentially one-use throw-away items. Other than springs, component parts need to be individually suited to high-speed plastics injection moulding, and collectively suited to high-speed automated assembly. Our own previous and continuing work on main body parts so mouldable in one piece, also on inner parts that are readily sequentially assembled together with a pre-loaded cartridge into the main body part, has been recognised as contributing significantly to achieving viable applicator production costs. The teaching hereof arises from such continuing work.

BACKGROUND TO INVENTION

Prior proposals for such applicators include providing for needle extension as a first stage in their use, i.e. having an as-supplied state with the needle retracted. Pre-treated drugs etc cartridges typically have fixed needles, in which case such first stage involves movement of the cartridge internally of the applicator. It is known for such movement to be by the same drive force as serves to discharge the cartridge contents through the needle by continuation of

such force application through and after cartridge movement for needle extension. It is further known, in relation to typical cartridges having a piston for expression of contents, for drive force application to rely on force transmission through incompressible liquid contents of the cartridge to achieve the first needle extension stage of movement of the cartridge. Indeed, such inherently double-action simplicity has been seen as intuitively self-evidently advantageous. Examples include EP0516473, which clearly accepts drug weepage through its needle during extension as an inevitability; also our PCTs WO93/23098 and WO95/35126 which are advantageous from practicality of highly economic production using one-piece moulded main body parts and inner parts carefully designed with a view to facilitating ease of high-speed assembly.

SUMMARY OF INVENTION

Viewed generally, this invention arises from the radical step of counter-intuitive questioning the above presumption as to advantage in force transmission through cartridge contents for initial needle extending cartridge movement, particularly taking issue with inevitability of some premature contents expression on the way to the needle reaching desired tissue penetration. Avoidance by relying on initial piston stiction (static friction) within the cartridge has been found not to be wholly problem-free. Whilst such stiction does typically represent substantially greater frictional resistance than sliding friction once the piston moves, this is subject to enough unpredictability to make detail design rather difficult. This is particularly so in finding truly viable balance of and with drive and needle retraction forces, typically provided by compressed springs. It is, of course, important to seek to achieve the highest degree of reliability along with smoothness of action for drugs etc administration.

Accordingly, it is one object of this invention to provide an alternative basis for hollow-needle applicator operation with capability for embodiment with reduction of problems and/or other relative advantage.

According to one structural aspect of this invention there is provided a releasable mechanical coupling effective as between a force applying actuator and a cartridge or carrier therefor, the coupling having cooperating parts on the one hand driven by the actuator and on the other hand driving the cartridge or

carrier therefor until released, and further cooperating provisions for positive release action on said driven and driving parts after prescribed movement thereof.

5 There can, with advantage, be a further stage involved in completing release of the driven and driving parts, perhaps especially for achieving full release at a prescribed movement that is problematic by reason of being very closely specified, say more closely than fits in with whatever movement is required for and during the positive release stage, and/or is subject to a particular limit, say by arrest at some physical abutment for the cartridge or carrier. This
10 further stage can be by automatic release of drive coupling engagement by other of said driven and driving parts, say at such arrest and by reason then of its reactive effect on such other engagement. In one implementation, this other engagement takes over or persists after positively released parts are disengaged and is more easily disturbed, say slides off or even breaks under shock loading.
15 Completion of final movement by some only of plural parts engagement provision after positive disengagement of the remainder is seen as another inventive aspect hereof, and has particularly appropriate application where drive force is substantially reduced by the time such positive disengagement is reached.

Typically, the same drive force as achieves said prescribed movement can
20 thereafter continue to act in discharging the contents of the cartridge, but not so acting relative to cartridge contents during such prescribed movement; indeed, can advantageously have no action on and apply no force to in-cartridge means (typically of piston type) for discharge pressuring of such contents until such positive releasing takes place.

25 Suitable said driven and driving parts can be as extensions from the actuator and from the cartridge beyond its occupation by its contents (or from any carrier for such cartridge), respectively. Typically such extensions can be oppositely directed and may cooperate either by registering engagement prior to positive disengagement by said further cooperating provision, or by non-
30 registering engagement of some intermediate part(s) movable by said further cooperating provision.

Suitable said further cooperating positive release means can be located

substantially at a position axially along a hollow applicator body that the cartridge or carrier reaches in said prescribed movement, conveniently as triggering part(s) projecting thereto from alongside the cartridge (or carrier) including alongside where cartridge contents are located.

5

Disengagement of the driven and driving parts can be by movement of said intermediate part(s), say part-rotation of an apertured member, say ring or disc, for aperture-registration with driving and triggering parts; or by relative displacement of the driving and driven parts, say by flexing of either or both of them out of registering mutual engagement, typically one of them moved by engagement with the further cooperating means.

10

Such displacing movement of a said driven part, even if radially outwardly by registering positive release means, should then result in unobstructed further passing of the release means into the actuator until desired cartridge contents discharge is achieved, preferably in a physically compact manner with displaced part portions at least partially within thickness of triggering parts of the further means. Non-registering driven and positive release parts, say as operated by some rotational intermediate member, facilitates physical compactness transversely of the applicator as such non-registering parts concerned can simply be at positions within the same transverse slice of space of the actuator.

15

20

Physical compactness can be further enhanced advantageously by complementary slotting of the cartridge extension to match and accommodate actuator parts concerned, including at the actuator's main spring-driven part so mutual entry or overlap means each is at least partially within the thickness of the other.

25

As foreshadowed above, preferred embodiments of this invention do seek to further rely on continuation of application of the same actuator drive force to discharge the cartridge.

30

Accordingly, preferred actuators have other force-transmitting part(s) that are ineffective until the mechanical coupling for needle extension is released, specifically effective to pressurise cartridge contents only after such release.

Another structural aspect of this invention is thus seen in an applicator drive actuator having two force-applying parts for different purposes, say one for

needle-extension movement of a said cartridge and the other for discharging contents of the cartridge, and one effective before the other but then ineffective while the other is effective. Rendering the one ineffective can, of course, be by the releasable mechanical coupling of the first structural aspect of this invention.

5 Suitable purpose-specific said force-applying parts can be as different extensions of or from the actuator, typically of axial-parallel nature relative to the actuator and applicator main body part accommodating the actuator, say one radially inside the other.

10 Provision for discharging cartridge contents is, of course, further preferably in conjunction with provision of means for achieving automatic needle retraction after desired discharge of cartridge contents. This further means advantageously includes purpose-specific releasable mechanical coupling, say conveniently associated with said other force-applying part(s) of the actuator.

15 Accordingly, a further structural aspect hereof is seen in an applicator drive actuator in operative association with two releasable mechanical couplings for different purposes, say one for needle-extending cartridge movement and the other for cartridge contents discharge needle retracting cartridge movement, and the one being released before the other and the other being effective to transmit drive force only after the one is released.

20 The one and the other said releasable mechanical couplings can advantageously be as those first and second above-mentioned, respectively.

25 It is highly advantageous in relation to high-speed automated assembly for both of these releasable mechanical couplings to be engaged at assembly, say as a sub-assembly, though the later released coupling will not be force-transmitting until the earlier released coupling is actually released.

30 For a said releasable mechanical coupling serving to discharge the cartridge contents then secure needle-retracting cartridge movement, it can be particularly advantageous for the related actuator extension as driving part and a piston rod as driven part for the cartridge piston to be relatively entrant each other at coupling release. This can be seen as shortening the overall effective length of parts involved in discharging cartridge contents, and such feature is also seen as an inventive structural aspect.

Positive coupling release for such shortening is achievable by way of a triggering provision involving part(s) of the cartridge piston rod as such, and this, too, is seen as an inventive structural aspect hereof, whether viewed as relatively movable piston rod parts or as trigger part(s) movable relative the piston rod as such.

Such triggering relative movement can very readily and most usefully be by way of deformation of deformable said cartridge piston as such when it reaches the end of the cartridge at the end of intended contents discharge, but with substantial force available from actuator drive spring compression, say up to 50% or more compression remaining, preferably about 60%. This can assure that substantially all of the cartridge contents is discharged through the needle, i.e. so that virtually no more than needle content is undischarged. This is important for highly expensive drugs as an ullage requirement has hitherto been the norm, i.e. the cartridge having over-fill by as much as 5% - 10% compared with actual desired dose as delivered, which may need to be very accurate indeed.

Accordingly, reduction of such ullage requirement is also seen as a significant inventive aspect hereof, particularly as involving length reduction of parts effective in cartridge contents discharge.

Suitable length shortening is achievable by partial entry of part(s) of the piston rod as such into coaxing extension of the actuator after release of the force-transmitting relation between them, which may be by deflection for directly engaging parts of the mechanical coupling concerned, or by movement of an intermediate member from drive-transmitting blockage to unblocking of at least some of the driving/driven parts concerned.

If found useful to do so, spring force can be used between the parts involved in length reduction, say by a compression spring interposed between the parts concerned and opposing any length-shortening movement, say to protect against premature coupling release due to hydraulic reactive back-pressure from the cartridge contents during pressurised discharge.

One suitable length-shortening provision comprises a piston rod with driven coupling extension parts to be deflected away from each other or

outwardly for coupling release and a triggering rod slidable in a bore through the piston rod from engagement with the driven coupling extension parts to spread them when the piston is deformed at reaching the end of the cartridge.

Another suitable length-shortening provision comprises a piston rod with driven coupling extension parts to be deflected towards each other or inwardly for coupling release and a triggering collar slidable about the piston rod from engagement with the driven coupling extension parts to clench them when the piston is deformed at reaching the end of the cartridge.

BRIEF DESCRIPTION OF DRAWINGS

Exemplary specific implementation for this invention is shown in and described relative to the accompanying diagrammatic drawings, in which

Figure 1 is an axial sectional view of one embodiment;

Figures 2A - D are related detail scrap views;

Figures 3A - D show its stages of operation;

Figures 4A - D are cross-sectional views at A-D of Figures 3A - D;

Figure 5 is an axial sectional view of another embodiment;

Figures 6A - D show its stages of operation;

Figures 7A - D are cross-sectional views at A-D of Figures 6A - D; and

Figures 8A - C illustrate details for rotational drive coupling and release.

DESCRIPTION OF ILLUSTRATED EMBODIMENTS

In the drawings, referring first to Figures 1 and 2A - D, an applicator 100 is shown with a hollow generally cylindrical body part comprising main portion 101A and relatively short forward portion 101B shown as typically of reduced section, the whole body part 101A,B being carefully designed and detailed as suited to being moulded in one-piece. Cross-sectional shapes other than circular are equally feasible, e.g. oval or polygonal or irregular.

The main body part portion 101A terminates in an open end 102 shown with a slight flare beyond internal peripheral groove 103 and external thickening grip formation 104 below end bead 105. The reduced section forward portion 101B terminates in returned end face 106 shown centrally apertured at 106A for passage of a hollow needle 107 through an inwardly flared re-entrant further return 108 for retaining a needle shield 109 that is suitably pierced by extension

of the needle 107, typically being made of non-curing elastomeric material.

The needle 107 and shield 109 are shown fixed and fitted in and to reduced end 110B of a hollow generally circular-cylindrical cartridge with a main portion 110A slidable in the body part including its forward portion 101B. The
5 reduced cartridge portion 110B is shown with a slightly enlarged end to aid retention of the needle shield 109.

The main cartridge portion 110A is shown with piston 111 and typically pre-loaded contents 112, further as extending (110E) beyond the full contents-accommodating position of the piston 111. An alternative to the cartridge to be
10 so extended (110E) would be for such extension (110E) to be of a carrier or holder for a standard cartridge. The piston 111 is of deformable material as will be described in relation to maximising expression of cartridge contents 112. Exterior of shoulder 110S between the main and reduced portions 110A, B of the cartridge is shown acted upon by a compression spring 113 seated at 114
15 about the re-entrant end return 108 of the forward body portion 110B. This compression spring 113 can further compress to allow cartridge movement up to abutment of the cartridge shoulder 110S (or part of a cartridge carrier/holder) and internal ledge 101L of the body portion 101B as will be described for needle extension.

20 Internal grooving 103 about the other end 102 of the main body portion (101A) is shown aiding secure location by external ribbing 115R of a plug 115 incorporating releasable capture provision 118 for actuator 120. The illustrated capture provision 118 is operative relative to a neck reduction groove 121G in end extension part 121 of the actuator 120, conveniently by way of slider part
25 119 with key-hole aperturing 119K that holds or releases the actuator extension 121 according to slider position controlled by knob or button 119S. On-end location and operation of applicator release slider operating knob or button as illustrated at 119S is neither essential nor particularly preferred. Indeed, push-operation from a side of the body part 101A short of its end has been
30 considered and may well be preferred for at least some practical implementations, say (see Figure 2D) with comfortably enlarged head 119H of the slider available to a user's digit, usually thumb, and feasibly recessed 101S and/or further with

a removable cover.

The plug 118 also has an inward extension 118E affording recessed seating 122S for head part 122 of the actuator 120 below the neck-grooved part 121, and defining outer seating 125S for actuator drive spring 125 acting on outward flanging 124F of main actuator part 124 extending from head part 122.

It will be appreciated that the drive spring 125 cannot move the actuator 120 until the extension part 121 is released from the capture provision 118.

The objectives of such released movement of the actuator 120 include first to move the cartridge (110A,B) for needle extension without reliance on application of force to the cartridge piston 111 thus not on force transmission through the cartridge contents 112, i.e. without involving either of piston stiction or hydraulic lock; and secondly only after such needle extension to apply force to the cartridge piston in pressuring the cartridge contents 112 for discharge through the needle 107.

For achieving the first objective, Figure 1 shows releasable mechanical coupling between (driving) coupling extensions 126 from the flanging 124F of the main actuator part 124 and (driven) extension(s) 110E of the cartridge (110A,B) beyond the full pre-load position of the cartridge piston 111.

The illustrated releasable coupling mechanism involves ends 126E of the actuator coupling extensions 126, shown inclined radially inwardly for force-transmitting engagement with registering cartridge extensions 110E; and releasable from such drive force transmitting engagement by radially outward deflection of the ends 126E. This releasing deflection is shown as involving positive deflecting action by triggering extension(s) 128 shown in fixed relation internally of the main body part (101A,B). Specifically, triggering extensions 128 are shown as axial-parallel projections from the reduced section of the forward body portion 110B into the main body portion 110A immediately about the main cartridge part 110A, specifically having advantageous sliding and locating relation therewith.

Feasible variations on this releasable coupling (126E/110E) include the cartridge (110A,B) being in a carrier having the coupling extensions 110E; and/or the radially relatively inward and outward relationship between the

coupling extensions 126E and 110E being reversed, i.e. the cartridge or carrier coupling extensions 110E being outward of the actuator coupling extensions 126, 126E and the triggering extension(s) 128 being radially located to suit; and/or the release deflection being of ends of the cartridge or carrier coupling extensions 110E, either alone or conjointly with some end deflection of the actuator coupling extensions 126.

Further specifically, see also Figure 2A, the deflectable ends 126E of the actuator coupling extensions 126 are indicated with hinge notch 126N shown open in Figure 2A but closed up in Figure 1, and part-bifurcation slotting 126S and tapering 126T to aid cooperation with end tapering 128T of the triggering extension(s) 128. The slotting 126S will be such as to accommodate the triggering extensions 128. Similar considerations apply to variation of such slotting provisions as between the coupling extensions 110E and 126E, i.e. including reversal and/or such formations of each as may cooperate conjointly for mutual deflection.

Figure 2B shows detail of the slotting of the flanging 124F of the actuator part 124, specifically contiguously at 124X to accommodate the triggering extension 128 and at 124Y to accommodate the drive coupling extensions 110E.

As should be apparent from Figure 1, but see also Figures 3A/B, the needle-extending movement of the cartridge 110A, B is accompanied by compression of the retraction spring 113, and is by an amount pre-set according to achieving abutment of the cartridge shoulder 110S and the internal ledging 101L of the forward body portion 101B. Strict coincidence between achieving this abutment and completing positive release action of the triggering extensions 128 can be desirable but is not essential, at least so long as there is some adequate small compliance, possibly small relative movement accommodation (e.g. flexure of the coupling extensions 126 and/or 110E) and/or a small final movement relying on stiction of the cartridge piston 111 or on hydraulic lock of cartridge contents 112 is permissible before/during actual positive release action by the triggering extension(s) 128.

One way to assure mechanical coupling right up to cartridge-arresting abutment is to use an effectively two-stage releasable mechanical coupling, say first stage along the lines described above but with another drive coupling element that is not so positively disengaged but will disengage automatically when the cartridge is finally arrested by abutment. Such other coupling element has load-bearing requirement less than the positively disengaged elements as the drive spring will be extended near to its maximum for needle extension.

Figure 2C in its various components shows a two-stage releasable mechanical coupling with an additional independently deflectable extension leaf 126A between those 126E positively deflected by spaced parallel triggering extensions 128A, B and with its end shaped for less purchase on cooperating coupling extension 110E so as to deflect for decoupling simply by reaction to arrest of the cartridge 110. For illustrative purposes only, Figure 2C drawing components show undeflected coupling engagements to the left and deflected dis-engagements to the right.

The second actuator objective, namely operation of the cartridge piston 111 to discharge the cartridge contents 112 through the needle 107, is also shown involving a releasable force-transmitting coupling associated with cartridge piston rod 131. Specifically, the engaged force-transmitting state of this coupling 130 is between deflectable coupling extensions 131E of cartridge piston rod 131 and coupling extensions 132E of centrally extending actuator part 132. The piston rod 131 is shown hollow about a trigger rod 133 with axial-parallel space 131S to accommodate the actuator coupling extensions 132E after release of the mechanical coupling 131E/132E. This release is also of a positive nature by action of end-tapering 133T of the trigger rod 133, shown going to a point. This trigger rod 133 can slide axially in the piston rod 131 to become operative for deflecting the coupling extensions 131E of the piston rod 131 in making desired release of the mechanical coupling 131E/132E. This release action is dependent on the cartridge piston 111 both reaching the end of the internal contents-accommodating space of the cartridge (110A,B) and being deformed thereat to move the trigger rod 133 as well as assure maximal discharge of the contents 112 of the cartridge (110A, B) as such.

The coupling extensions 131E can be as inverted forms of what is shown in Figure 2A, even including bifurcation if the trigger rod is longitudinally ribbed, ridged or splined, i.e. with any such ribbing, ridging or splining accommodated in such bifurcations.

5 What is shown in Figures 2A, B is well suited to embodiments with three or four angularly spaced sets of inter-acting coupling extensions for each releasable mechanical coupling, typically equi-spaced about the applicator axis. Accordingly, the axial sectional views of Figs. 1 and 3A - D may need to be viewed as angled differently to each side of axial centre-lines. However, two
10 each is practical, as in Figures 4A-D to be described later.

Full sequential operation of the applicator of Figure 1 will be apparent from Figures 3A - D, specifically as-supplied state in Figure 3A with the actuator 120 held by the capture/release provision 118, the actuator drive spring 125 fully compressed and the mechanical coupling 126E/110E engaged (also the
15 releasable mechanical coupling 131E/132E); then released state in Figure 3B with the actuator 120 having been moved by the drive spring 125 to complete needle extending cartridge movement at abutment of the cartridge shoulder 110S with the body ledging 101L, and release of the actuator/ cartridge drive coupling 126E/110E by the triggering extensions 128; followed in Figure 3C by
20 discharge of cartridge contents 112 with the mechanical coupling 131E/132E still engaged up to deformation of the piston 111 and release of such coupling 131E/132E by the trigger rod 133 deflecting the piston extensions 131E; and finally in Figure 3D retraction of the discharged cartridge 110A, B and its needle 107 fully into the body part (101A, B) with the coupling extensions 132E of the
25 actuator 120 entrant the cartridge piston space 131S about the trigger rod 133, and the cartridge or carrier coupling extensions 110E and trigger extensions 128 passing through actuator flanging 124F and into slotting 124Y (started at Figure 3C stage).

30 The cross-sections of Figures 4A - D pertain to two-element releasable mechanical couplings 126E/110E and 131E/132E, the elements being in diametric relation and with main body guidance by way of ribs and grooves 101G/126R. Fig. 4C shows the coupling extensions 126E deflected into release

(compared with Fig. 4A), and Fig. 4D shows the actuator part 132 entrant the cartridge or carrier extension 110E (compared with Figure 4B).

Turning to the embodiment of Figure 5, differences compared with Figure 1 reside with realising the second actuator objective, specifically regarding its releasable mechanical coupling for cartridge discharge. This actuator 500 is thus as for the actuator 100 of Figure 1 save for its cartridge discharge piston rod 531 being within bottom-flanged or inverted top-hat section triggering collar 533 with an axial through-bore 533B and space 533S outside its reduced section upstand 533U for accommodating walling of tubular extension 532E of actuator 532 after mechanical coupling release for cartridge contents discharge.

The releasable mechanical coupling shown involves coaction between free end rim 532R of the tubular actuator extension 532E and splayed coupling extensions 531E from the inner end of piston rod 531 in relative sliding relation with the collar 533 in its bore 533B during deformation of piston 511 at reaching the end of the cartridge 510. This relative sliding (531/533) results in the collar upstand 533U acting as a trigger ring in aiding release of the coupling 531E/532E, specifically radially inward deflection of the extensions 531E of the piston rod 531.

The piston rod 531 is also shown with its coupling extension 531E partially split to present longer radially inward extensions 533F for guidance and assembly-aiding relation with the inner surface of the actuator extension tubular extension 532. An alternative for guidance would be for ends of each of the coupling extensions 531E to be stepped.

The releasable coupling 531E/532E is of an essentially similar nature to what is shown in our above-mentioned PCT applications, and full sequential automatic operation of the applicator 500 is believed to be apparent from the stages shown in Figures 6A - D corresponding to as-supplied, needle extension, cartridge contents discharge and retraction of cartridge/needle, respectively; and the cross-sections of Figures 7A - D, bearing in mind general advancement of references by 400 compared with Figures 1 - 4 and specific differences noted above for Figure 5.

As illustrated for the applicator embodiments of Figures 1 - 7, it is

feasible and advantageous for the transverse/radial offset requiring deflection for release to be accommodated compactly within the transverse/ radially consecutive thicknesses of the coupling extensions 126/526E and the triggering extensions 128; and likewise for elements 131/132E at cartridge discharge producing analogous results for elements 532E/533U of Figure 5.

Such transverse/radial compactness can be enhanced to the extent of effectively "losing" one of those thicknesses if the cooperating elements are out of angular registration, say side-by-side, and coupling/ decoupling is shown relying on rotation of an apertured interposed ring, see for example Figures 8A, B.

In Figure 8A, drive coupling ring 850 has an operative width affording outer angularly spaced apertures 851 and 852 and inner angularly spaced apertures 853. The apertures 851 have side tapers 851T to cooperate with side tapering 828T of triggering extensions 828 to rotate the ring 850 to a position where the apertures 851 afford full clearance to the triggering extensions 828. The apertures 852 are next to drive engagement positions 854 for mechanical coupling extensions 826 from a spring-driven drive actuator (not shown). This drive engagement will prevail until rotation of the ring 850 by the triggering extensions 828 brings the apertures 851 into clearance registration with the drive coupling extensions 826. The inner apertures 853 are next to engagement positions 855 for driven mechanical coupling extensions 810E from a cartridge or carrier therefor (not shown). These apertures 853 will afford full clearance for the driven coupling extensions after rotation of the ring 850 by the triggering extensions 828, to allow a retracted state equivalent to that of Figure 3D, i.e. overlapping the length of the drive spring engaged part of the actuator part (120 in Figure ??) without re-compression of the actuator drive spring (not shown but engaging the ring 850 at the outer apertured part of its width). It will be appreciated that the ring 850 would not pass the driven flange of the actuator, so could be an apertured disc, say with boss formation(s) at and radially inside the position shown for the inner ring edge to either or both sides of the disc so as to aid assembly, see at 850B in Figure 8B.

Rotational drive coupling and release is equally feasible for the second mechanical coupling operative for retraction of the discharged cartridge and its

5 needle. Equivalents to outer aperturing 851/852 of Figure 8A would suffice where the actuator drive coupling extensions and release triggering extensions concerned are angularly spaced at the same radial positions. Figure 8C shows a drive coupling ring 860 where the triggering extensions 831 are radially inside the actuator drive coupling extension 832E, and outer and inner apertures 851, 862 correspond thereto, respectively. The extensions 831 can be upstands from a collar 831C. As being much as described for the outer apertures of Figure 8A, rotation of the ring 860 is by mutual engagement of tapers 831T/861T and results in full clearances 631/861 and 832E/862.

10 Generally, embodiments of this invention most readily facilitate design to whatever extensions and retractions may be required or desired, including particularly allowance for accommodating to maximal adverse tolerances.

17

FIG. 1

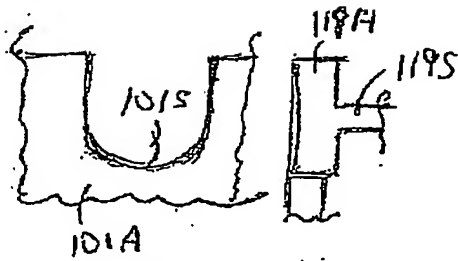
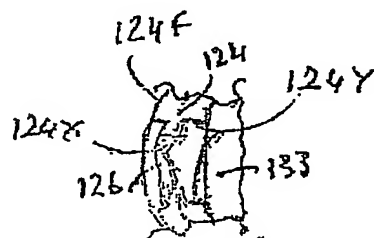


FIG. 2D



F/G 2B

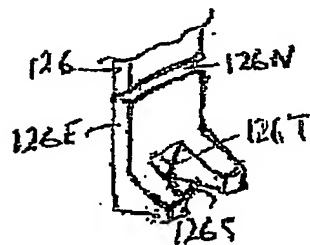
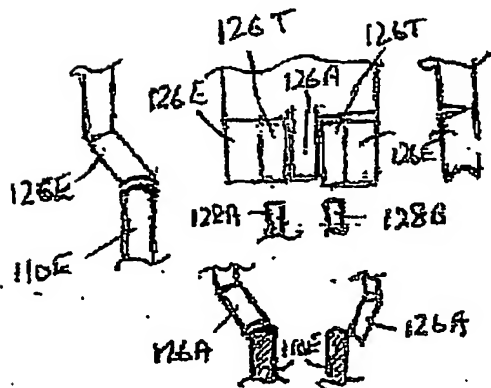
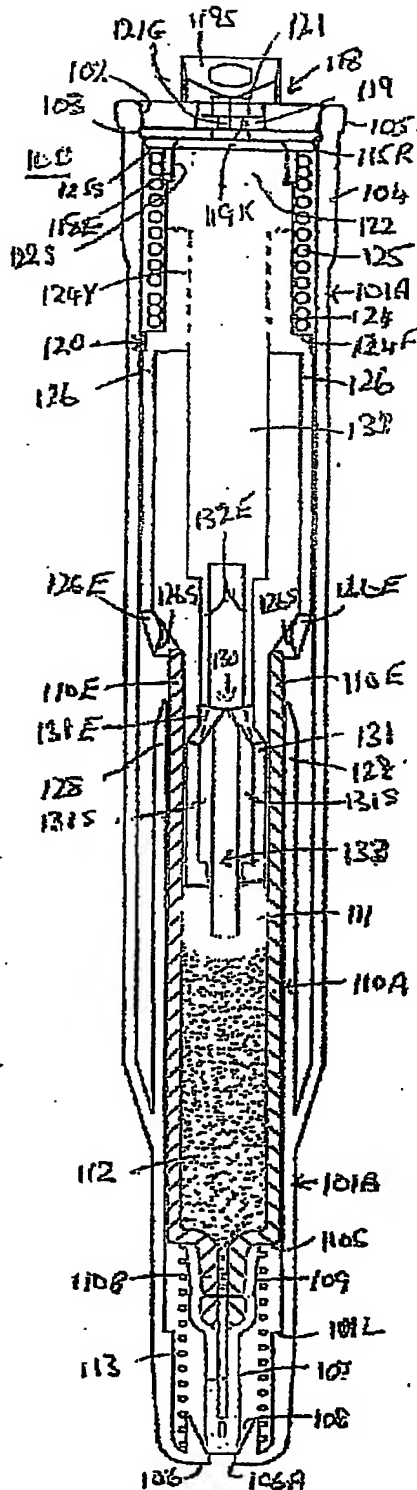


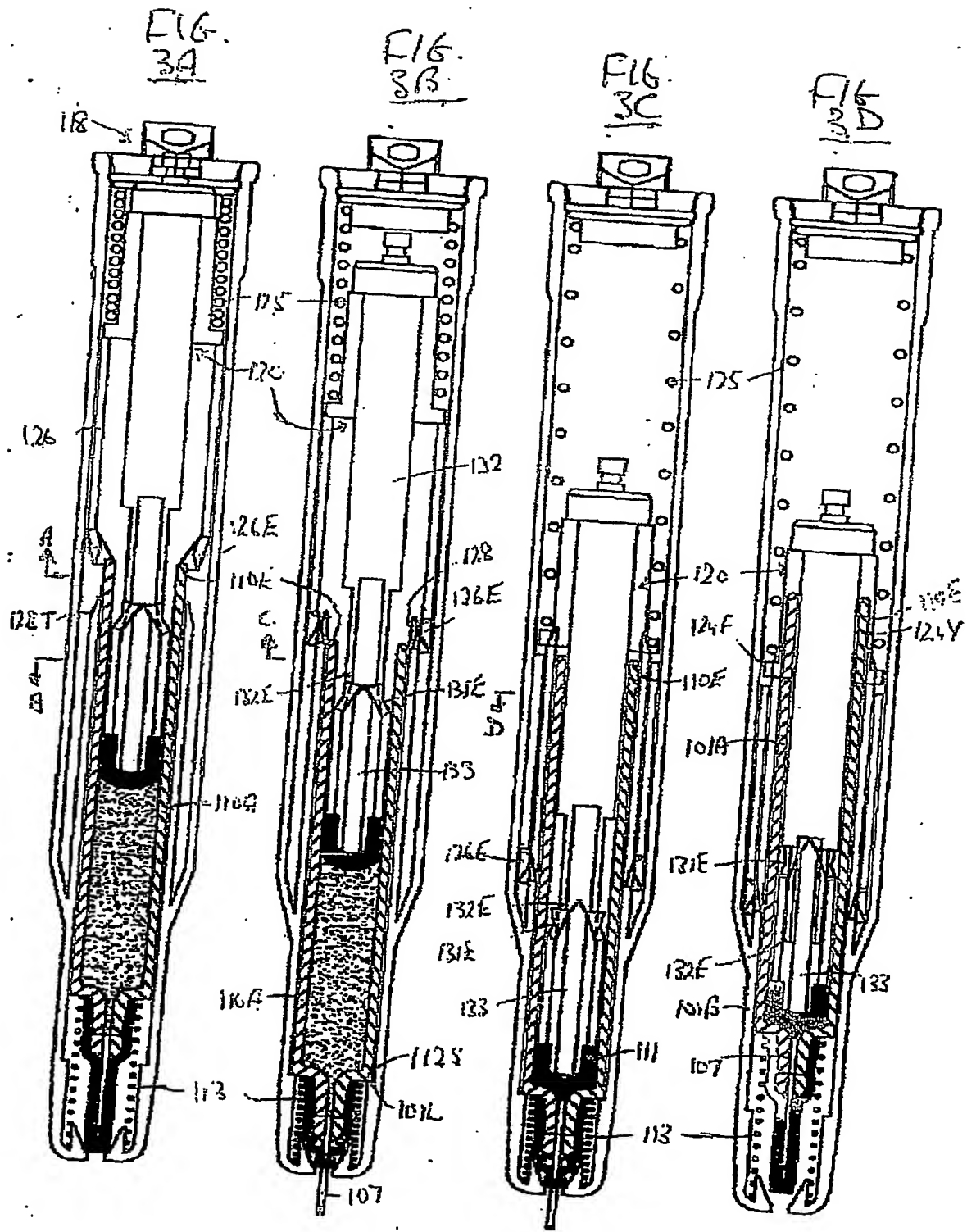
FIG. 2A



F16.2C



2/7



3/7

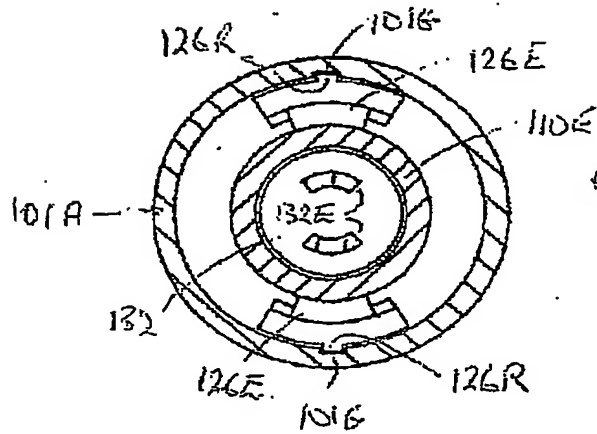


FIG. 4A

FIG. 4B

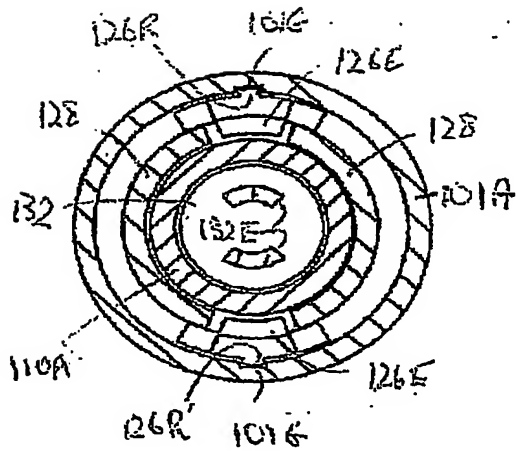
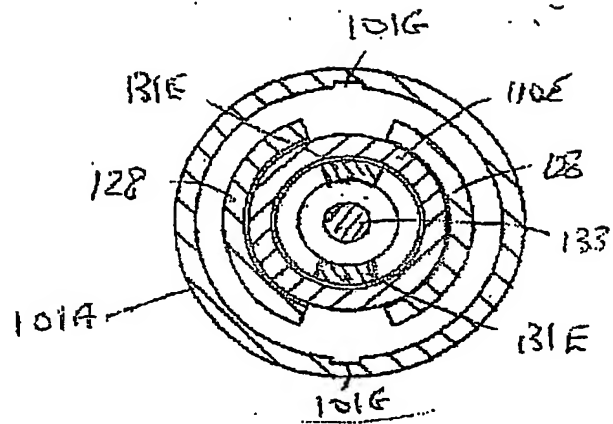
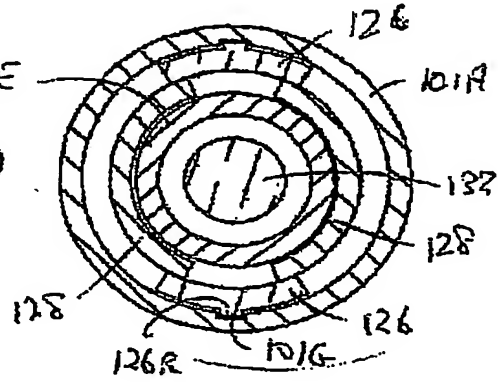


FIG. 4C

FIG. 4D



4/7

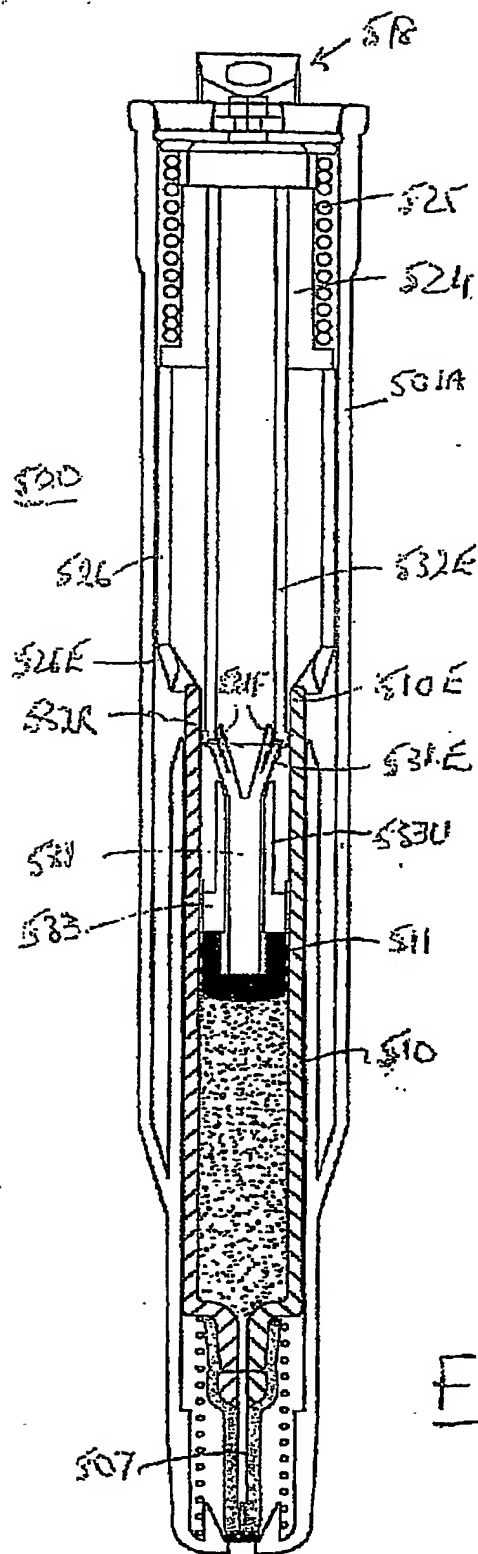
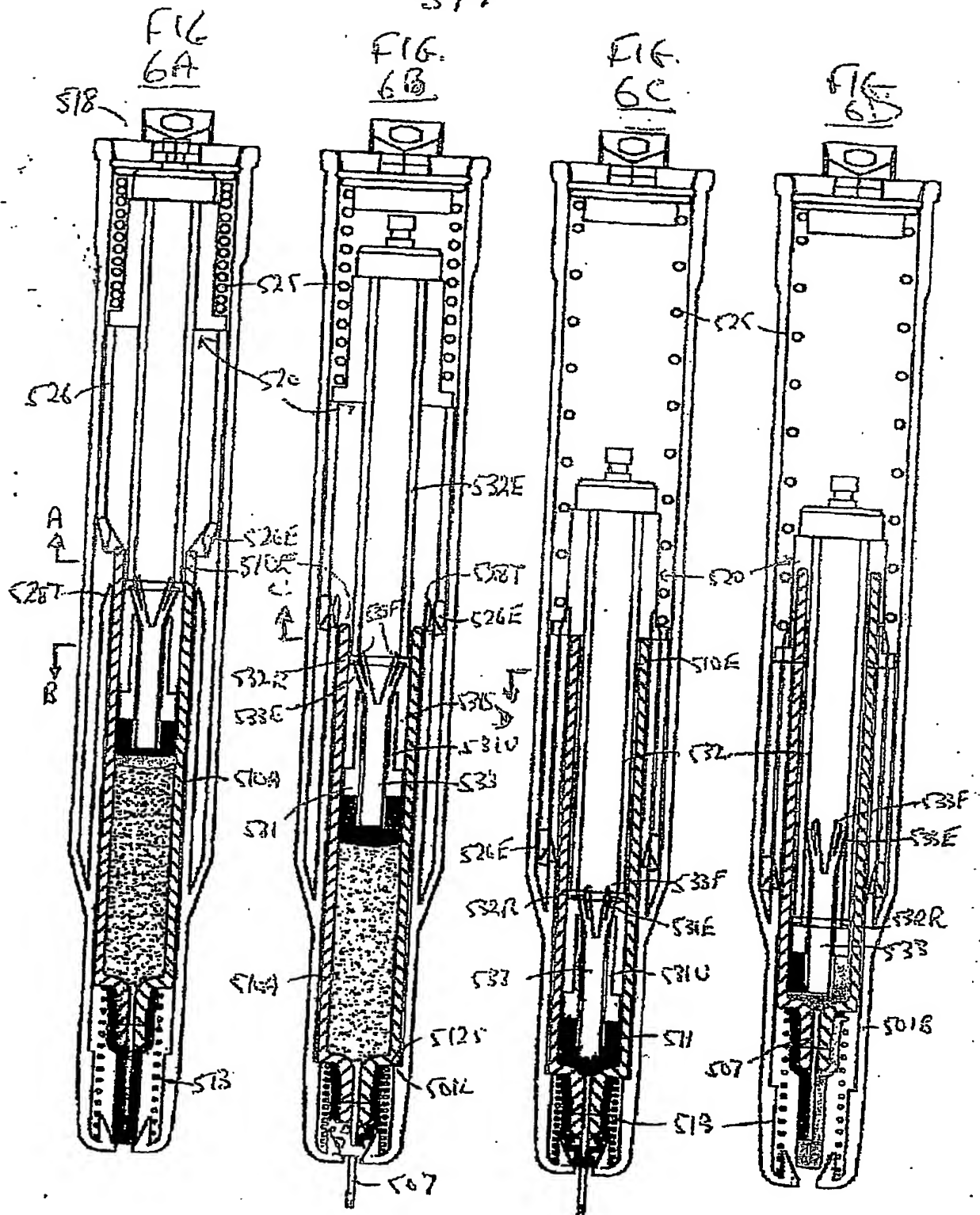
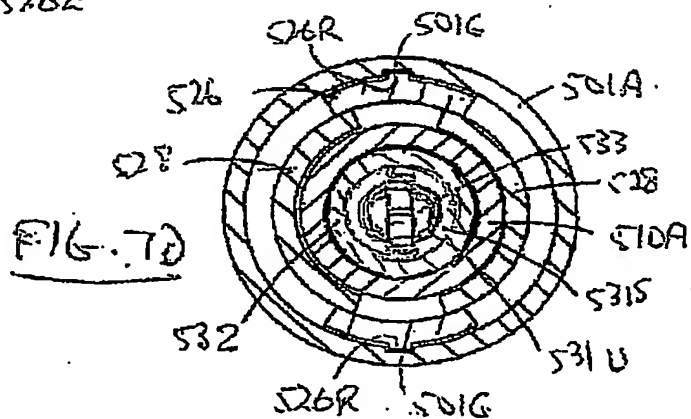
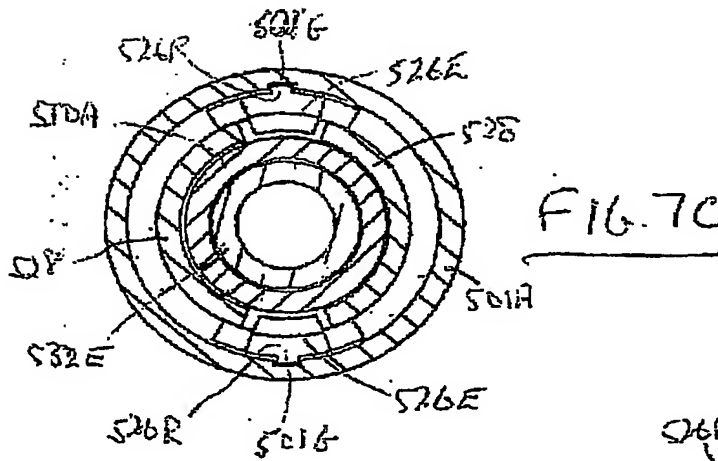
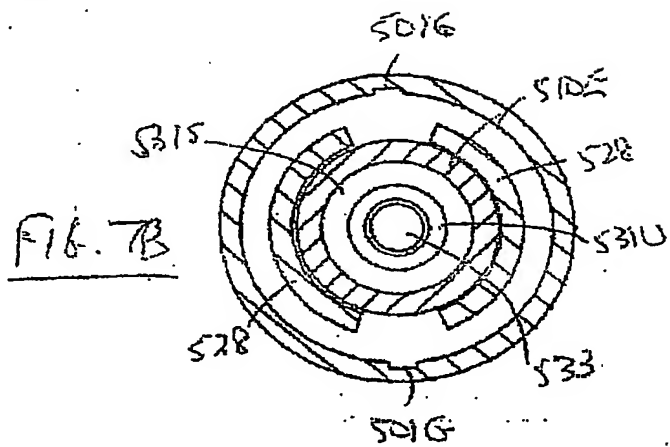
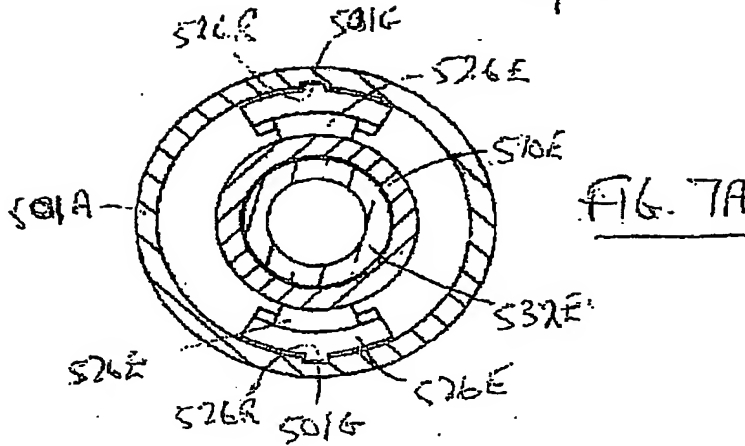


FIG. 5

5/7



6/7



7/7

FIG. 8A

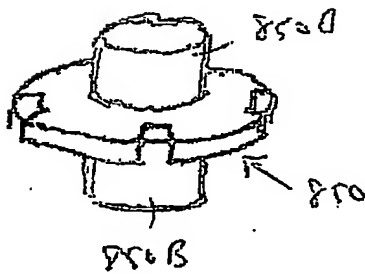
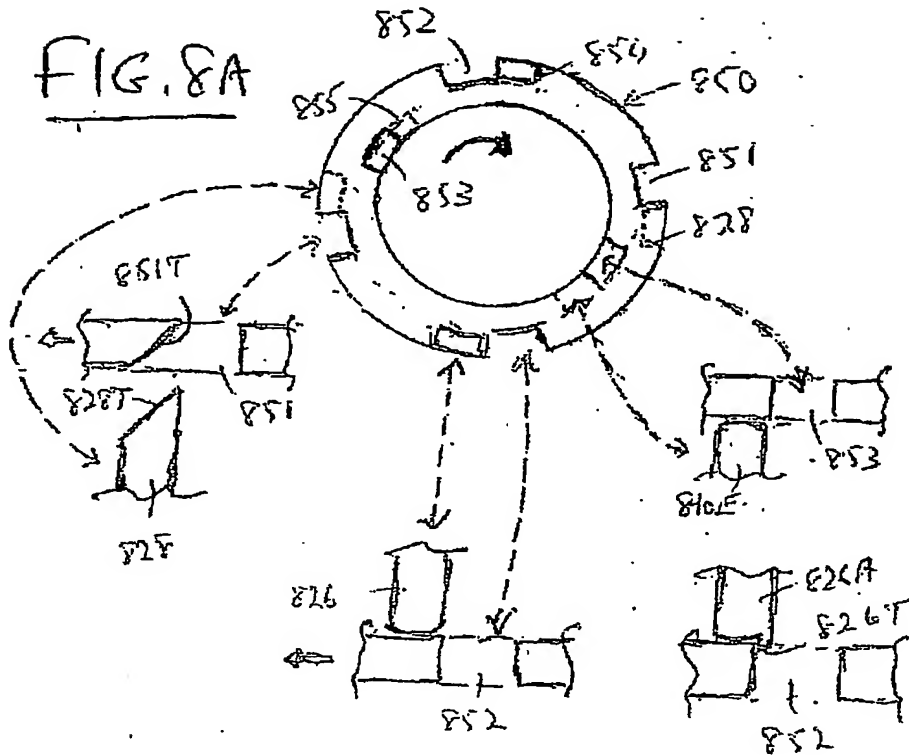
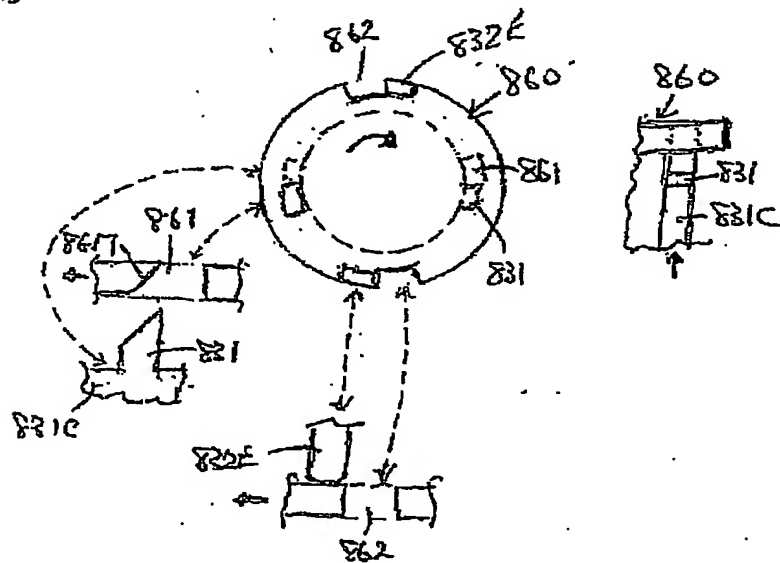


FIG. 8B

FIG. 8C



**This Page is Inserted by IFW Indexing and Scanning
Operations and is not part of the Official Record**

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- ☐ **BLACK BORDERS**
- ☐ **IMAGE CUT OFF AT TOP, BOTTOM OR SIDES**
- ☒ **FADED TEXT OR DRAWING**
- ☐ **BLURRED OR ILLEGIBLE TEXT OR DRAWING**
- ☐ **SKEWED/SLANTED IMAGES**
- ☐ **COLOR OR BLACK AND WHITE PHOTOGRAPHS**
- ☐ **GRAY SCALE DOCUMENTS**
- ☐ **LINES OR MARKS ON ORIGINAL DOCUMENT**
- ☐ **REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY**
- ☐ **OTHER:** _____

IMAGES ARE BEST AVAILABLE COPY.

As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.